Independent Verification & Validation Facility	**Corrective and Preventive Action**	**IVV 14 Revision: J Effective Date: October 2002**

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APPROVAL SIGNATURES		**DATE**
Greg Blaney (original signature on file)	QMS Management Representative	10/18/02

REVISION HISTORY			
Rev No.	Description of Change	Author	Effective Date
Initial	Initial Release	John Griggs IT/204	05/01/98
A	Section 2.0,3.0,5.0 And 6.0 were modified and added flow chart.	Siamak Yassini IT/332	07/23/98
B	Quality Record - format change, modified section 2.2	Siamak Yassini IT/332	08/26/98
C	Consolidated forms	Siamak Yassini IT/332	01/28/99
D	References to Ames Quality Manual replaced with references to IV&V Facility Quality Manual Updated Section 5.1.4 & 6.1.2	Siamak Yassini IT/332	09/10/99
E	Adding Track wise automated tool section 3.3	Siamak Yassini IT/332	3/30/00
F	Format and Number changes; Delete Reference to Ames Research Center	Griggs	12/06/00
G	Significant re-write to accommodate current process	Griggs	04/03/01
H	Revise severity codes to define “immediate”, also require corrective action plans	Griggs	9/13/01
I	Revise to include lower tier action tracking systems, and to modify the automated flow to allow staff to enter CAR/PARs	Griggs	6/6/02
J	Clarify initial assignment of CAR/PAR to Management Representative; also clarify use of IVV Form 1005 as backup to Trackwise	Griggs	10/21/02

REFERENCE DOCUMENTS	
Document Number	Document Title
IVV QM	IV&V Facility Quality Manual
IVV 16	Control of Quality Records
IVV 17	Internal Quality Audits

1.0 Purpose

The purpose of this System Level Procedure (SLP) is to define the corrective and preventive action processes at the NASA IV&V Facility that tracks the identification and resolution of product and service nonconformances and customer complaints.

The processes include the formal CAR/PAR tracking system, and three lower tier action tracking systems that support internal objectives.

2.0 Scope

This procedure applies to all processes, products, and services found nonconforming or potentially nonconforming pursuant to the IV&V Facility's Quality Management System (QMS).

3.0 Definitions and Acronyms

3.1 Nonconformance

A lack of compliance to a specified process or procedure associated with the Facility's Quality Management System, a nonconforming product, or a deficiency in the Quality Management System itself. For the purposes of this procedure, nonconformances will be categorized into three levels of severity.

3.1.1 Major - a quality system deficiency exists; a nonconforming product is issued and the nonconformity has a significant effect on customer success, safety or resources; lack of documented procedures, documented procedures are not being implemented consistently, or a series of minor nonconformities indicated an overall quality system weakness which has an adverse effect upon overall product quality.

3.1.2 Minor - a defined system exists with an acceptable level of implementation, however, there are minor discrepancies or lapses in discipline; a nonconforming product is issued and the nonconformity has little or no effect on the customer

3.1.3 Observation - an issue noted by an auditor that may lead to a nonconformanity if not corrected, a suggestion to improve a process, or editorial corrections to a procedure (i.e. typing errors, misspelling, etc.).

3.2 Corrective Action (CA)

Action taken to eliminate the cause(s) of an existing nonconformity, defect or other undesirable situation with a product or process in order to prevent recurrence.

3.3 Preventive Action (PA)

Actions determined from recognition of issues which could lead to nonconformities, or the analysis of data to detect trends and identify causes that may result in future nonconformances.

3.4 Corrective/Preventive Action Request (C/PAR)

A C/PAR is the documentation of a nonconformance or potential nonconformance. C/PARs can result from multiple activities or come from multiple sources (i.e. internal or external audits, actions from management's review of the Quality Management System, customer complaints, etc.).

3.5 TrackWise

An automated tool utilized by the IV&V Facility to capture, track, and report on C/PARs.

3.6 Product

A product is the result of activities or processes. IV&V products may include service, software, analysis reports, or a combination of these.

3.7 Corrective and Preventive Action (C&PA) Manager

The person designated by Facility management responsible for managing the corrective and preventive action system.

3.8 IV&V Facility QMS Management Representative

Member of the Facility Management team assigned to oversee the operation of the Quality Management System to a) insure that processes needed are established, implemented and maintained; b) Reports to top management on the performance of the QMS and needs for improvement; and c) ensures promotion of awareness of customer requirements throughout the organization.

3.9 Assignee

The person assigned action for a C/PAR by the Management Representative.

3.10 Initiator

Individual staff member/contractor working within the QMS, noting need for change or improvement.

3.11 Lower tier action tracking

Administrative, Project Management, and Research Management action tracking systems not requiring Facility wide access are used for internal process tracking of actions, including delivery dates. etc. These systems support the CAR/PAR system, and significant issues are upgraded into the CAR/PAR system. Procedures for these systems reside with the owner.

The Administrative action tracking system is controlled by the Directors office, and tracks administrative actions.

The Project Manger's action tracking system is internal to the Project Management structure, tracking actions from the Project Manager's meetings. In the PM meetings, notes are taken and stored on the Facility's shared drive. Recorded in those notes are action items assigned during the PM meetings. Often these AIs are simple, one-time items which are taken care of and closed. AIs from previous meetings are reviewed and if not completed, are recorded once again in the meeting minutes, appearing weekly until the action is closed. If an AI is deemed to be systemic to the Facility or can effect the quality of the Facility's products, it will be recorded in the CAR/PAR system rather than as an AI.

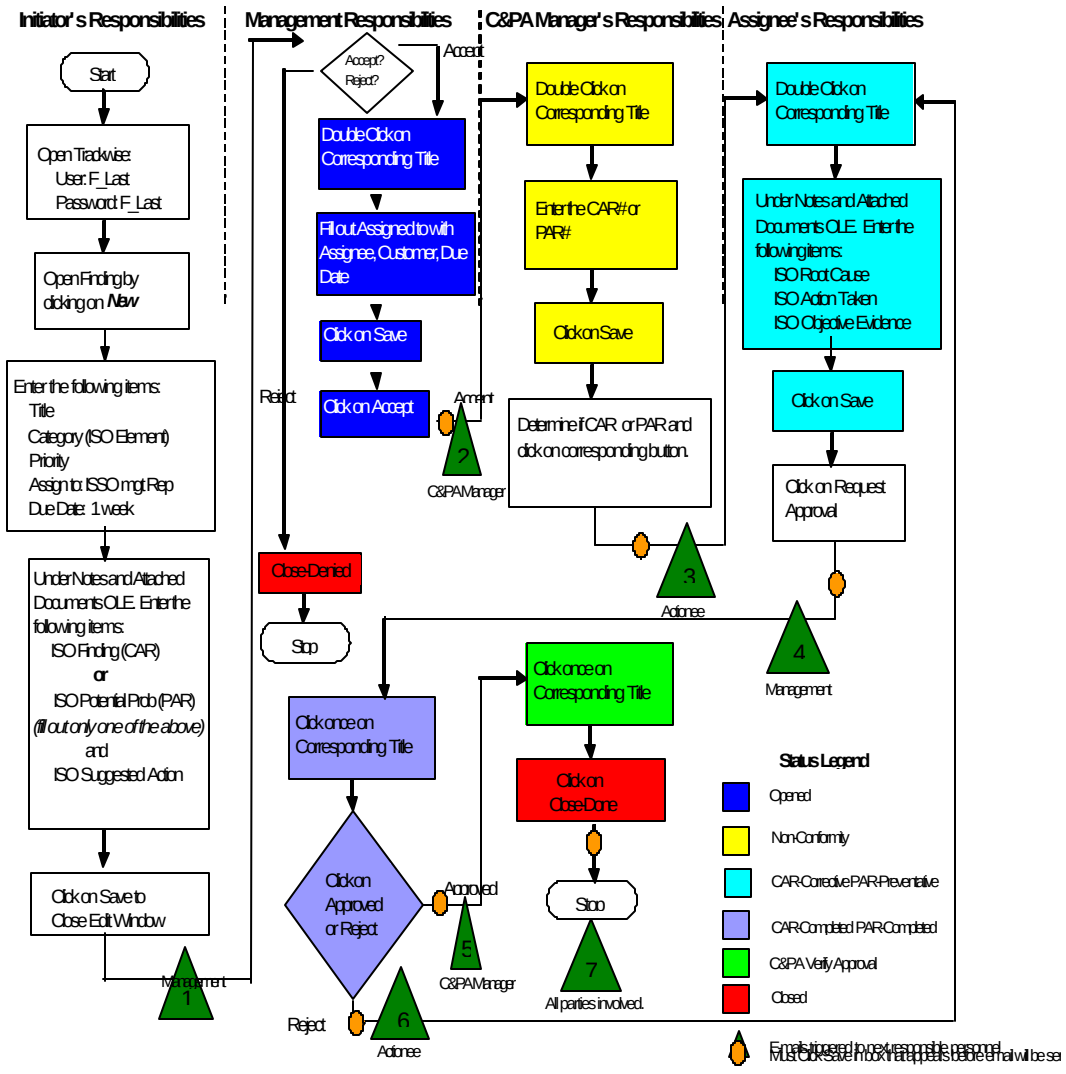
The research group maintains an informal action item tracking database within the Center Initiative Management (CIM) tool. The primary purpose of this database is to track the progress of day-to-day assignments and suspenses. In that context, it supplements the CAT/PAR system. Items of significance to the entire Facility staff must still be entered into the CAR/PAR system.

4.0 Flowchart

The process flow for Corrective and Preventive Action is depicted in the flowchart on the next page. The TrackWise flow describes the responsible persons and actions

for each step of the corrective and preventive action tracking process, from origination through closure.

TrackWise Process Flowchart



5.0 Responsibilities

5.1 QMS Management Representative

The Management Representative is responsible for the following:

5.1.1 Insure the corrective and preventive action process is established, administered, and utilized to maintain Facility Quality Management System process improvement.

5.1.2 Insure C/PARs are assigned to appropriate personnel with due dates identified.

5.1.3 Insure timely responses to C/PARs by assigned personnel.

5.2 Corrective and Preventive Action (C&PA) Manager

The C&PA Manager is responsible for the following:

5.2.1 Establishing and maintaining a system for corrective and preventive action.

5.2.2 Administering control of the C/PAR process.

5.2.3 Resolving conflicts and/or misunderstandings of required actions.

5.2.4 Preparing the Corrective and Preventive Action Management Status Report.

5.3 All Personnel

Any IV&V person subject to the scope of the Facility Quality Management System is responsible for entering a C/PAR if a nonconformance or a potential nonconformance is observed within the Facility's Quality Management System.

5.4 The Assignee

The Assignee is responsible for the following actions when a C/PAR is submitted and assigned to them by the QMS Management Representative.

5.4.1 Determine and document the root cause(s) of the nonconformance.

5.4.2 Identify, document, and implement required changes to address the C/PAR.

5.4.3 Ensure that all applicable data, including incorporated changes to operating practices, are documented.

5.4.4 Submit responses in a timely manner to the C&PA Manager.

A CAR with a severity of Minor or Observation, which is expected to require over 30 days to resolve and implement requires a Corrective Action Plan to be submitted and approved by the QMS Management Representative within 30 days of assignment, and filed within the CAR/PAR system

A CAR with severity of Major requires completed corrective action or an approved corrective action plan within 2 weeks.

A PAR will be assigned an appropriate due date by the QMS Management Representative when assigned.

5.4.5 Request line management support when required for timely response and closure.

6.0 Procedure

A C/PAR is originated whenever a current or potential nonconformity warrants a root cause analysis and corrective or preventive action because the nonconformity has or may have an effect on the quality of the products or services the IV&V Facility produces.

6.1 Originate a Corrective or Preventive Action

Any person subject to the NASA Quality System observing a nonconformance or potential nonconformance shall initiate a corrective or preventive action.

6.1.1 The identifier/originator of the nonconformance shall initiate a C/PAR by entering the following information into the TrackWise system:

- A brief title of the nonconformance
- The severity of nonconformance (for CARs)
- The category (Quality System process or procedure) affected
- A detailed description of the nonconformity
- Any suggested action
- Assigned to: IV&V Facility QMS Management Representative.
- Due Date: 1 week hence

6.1.2 The identifier/originator shall then save the C/PAR into the system; the system will notify the QMS Management Representative for evaluation and assignment. (Note: using the Save+ button performs the same function as the Save button, but leaves the system open ready to enter another C/PAR.)

NOTE: Form IVV 1005, Finding Report, may be used to initiate a CAR or PAR if Trackwise is not available. In that case, forward the completed form to the C&PA Manager for action.

6.2 C/PAR Evaluation and Assignment

Based upon the data submitted, the QMS Management Representative shall either accept the C/PAR and designate an Assignee for the investigation and resolution action or close the C/PAR because it is not a nonconformance.

6.2.1 If the C/PAR is valid, the QMS Management Representative shall designate an Assignee for the investigation and resolution action with an associated due date and indicate acceptance in TrackWise. The TrackWise system will then notify the C&PA Manager that an accepted C/PAR needs to be processed.

6.2.2 If the C/PAR is determined to be invalid, the Management Representative shall indicate rejection in TrackWise. This will close the C/PAR and no further action is required.

6.3 Logging and Tracking of C/PAR

The C&PA Manager will perform the following actions upon notification of an accepted C/PAR:

6.3.1 Assign a C/PAR number.

6.3.2 Indicate whether it is a corrective or preventive action.

6.3.3 Save the C/PAR. This will cause the TrackWise system to notify the Assignee that an accepted C/PAR has been assigned to them for investigation and resolution with a due date indicated.

6.4 Processing of C/PAR

The Assignee shall perform the following actions upon notification of an assigned C/PAR action.

6.4.1 Investigate, document, and implement the required corrective and/or preventive actions in the Quality System processes or procedures.

6.4.2 Enter Root Cause information into TrackWise

6.4.3 Enter Action Taken information into TrackWise

6.4.4 Enter Objective Evidence showing resolution of nonconformity into TrackWise

6.4.5 Save the C/PAR in TrackWise

6.4.6 Click on Request Approval in TrackWise, and click on Save. This will submit the completed C/PAR to the QMS Management Representative for acceptance or rejection of the resolution implemented by the Assignee.

6.5 Management Review of C/PAR Resolution

The Management Representative shall determine if the resolution actions taken by the Assignee are acceptable to eliminate or preclude the nonconformance identified in the C/PAR.

6.5.1. Acceptable C/PAR Resolution If the Assignee's actions taken in response to the C/PAR is adequate and acceptable to the Management Representative, the QMS Management Representative will approve the resolution in TrackWise. This will cause the system to submit the C/PAR to the C&PA Manager for closure.

6.5.2 Unacceptable C/PAR Resolution

If the Assignee's actions taken are not adequate or acceptable, the C/PAR will be rejected and returned to the Assignee to work again. The Assignee must again go through the request for approval process after re-working the C/PAR.

7.0 Metrics

The C&PA Manager shall report metrics to the management representative at the Quarterly Management Review. Such metrics may include the following:

7.1 Total number of C/PARs open

7.2 Number of C/PARs opened during reporting period

7.3 Number of C/PARs closed during reporting period

7.4 Number of open C/PARs where no action was taken during reporting period

7.5 Age of all open C/PARs

8.0 8.0 Records

The following records will be generated per this procedure and will be managed in accordance with IVV 16, Control of Quality Records.

Document Name and Identification Number	User Responsible for Record Retention	Retention Requirement	Location
C/PAR Database from Track wise tool (or IVV form 1005)	C/PAR Manager	5 years	C/PAR Manager Folder